IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMA S.A., SANOFI-AVENTIS U.S., LLC Plaintiffs, v. HOSPIRA, INC., Defendants.	)	C.A. No. 1:07-cv-00721 (GMS)

HOSPIRA'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Hospira, Inc., by and through its undersigned attorneys, hereby submits its Answer, Affirmative Defenses, and Counterclaims. Except as stated, Hospira denies the allegations contained in Plaintiffs' Complaint, and maintains that Plaintiffs (collectively referred to as "sanofi-aventis") are not entitled to any relief.

1. Aventis Pharma S.A. is a French corporation with its principal place of business in Paris, France. Sanofi-aventis U.S., LLC is a Delaware corporation with its principal place of business in Bridgewater, New Jersey.

ANSWER: On information and belief, Hospira admits the allegations of paragraph 1.

2. Sanofi-aventis is in the business of developing, manufacturing, and selling a wide variety of consumer products, including pharmaceutical products. Sanofi-aventis U.S., LLC is the holder of approved New Drug Application No. 020-449 for the active ingredient docetaxel, which has the proprietary name Taxotere®. Taxotere® is sold by sanofi-aventis throughout the United States, and it has been approved by the FDA for seven indications. Worldwide, Taxotere® is marketed in over 100 countries and used for the treatment of, *inter alia*, breast, lung, prostate, gastric, and head and neck cancer.

ANSWER: On information and belief, Hospira admits that sanofi-aventis is in the business of manufacturing pharmaceutical products and is the holder of NDA 020-449, and that it sells

Taxotere®. Hospira is without sufficient information either to affirm or deny the remaining allegations in this paragraph and therefore denies them.

3. Upon information and belief, Defendant, Hospira is a Delaware corporation with its principal place of business at 275 Field Dr., Lake Forest, Illinois 60045. Upon information and belief, Hospira is a manufacturer of specialty injectable pharmaceuticals and of medication delivery systems.

ANSWER: Hospira admits the allegations of this paragraph.

NATURE OF THE ACTION

4. This is a civil action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(e). This action relates to a New Drug Application ("NDA") filed by Hospira with the United States Food and Drug Administration ("FDA") for approval to market a copy of sanofi-aventis' highly successful Taxotere® pharmaceutical products that are sold in the United States.

ANSWER: Hospira admits that this is an action alleging patent infringement pursuant to § 271(e) of the Patent Act and relates to an NDA filed by Hospira. Hospira denies the remaining allegations of this paragraph.

JURISDICTION AND VENUE

5. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Hospira admits that subject matter jurisdiction is proper.

6. Upon information and belief, Hospira is incorporated in Delaware.

ANSWER: Hospira admits the allegation of this paragraph.

7. This court has personal jurisdiction over Hospira.

ANSWER: Hospira admits the allegation of this paragraph.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

ANSWER: Hospira admits that venue is proper in this judicial district.

BACKGROUND

9. Upon information and belief, Hospira has filed with the FDA in Rockville, Maryland, New Drug Application No. 22-234 under 21 U.S.C. § 355(b)(2) (also known as a 505(b)(2) application), to obtain FDA approval for the commercial manufacture, use, and sale of a docetaxel injection product in the following dosage forms: 20mg/2ml, 80mg/8ml, and 160mg/16ml. Hospira filed its NDA No. 22-234 to obtain approval to market a generic form of docetaxel injection solution, which is currently marketed by sanofi-aventis under the brand name Taxotere® (docetaxel) Injection Concentrate, before the expiration of certain sanofi-aventis patents, including U.S. Patent Nos. 5,714,512 and 5,750,561.

ANSWER: Hospira admits that it filed a 505(b)(2) application to obtain approval for a docetaxel injection product, that sanofi-aventis has a docetaxel injection product marked under the brand name Taxotere®, and that Hospira's notice letter sent to sanofi-aventis included U.S. Patent Nos. 5,438,072; 5,698,582; 5,714,512; and 5,750,561. Hospira denies the remaining allegations of this paragraph.

10. On behalf of Hospira, Michelle Murray of Winston & Strawn, LLP, sent a letter dated September 28, 2007, to Gerald V. Dahling of Aventis Pharmaceuticals Inc. via facsimile and certified mail, to Gregory Irace and Eric Phillips of sanofi-aventis U.S. via facsimile and certified mail, and to Aventis Pharma S.A. via facsimile and registered mail to provide notice, pursuant to 21 U.S.C. § 355(b)(3)(B), that Hospira had filed NDA No. 22-234 with respect to docetaxel injection solution in a variety of dosage forms (20mg/2ml, 80mg/8ml, and 160mg/16ml). The letter further provide notice that Hospira had filed with the FDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), a certification ("Paragraph IV certification") alleging that U.S. Patent Nos. 5,438,072; 5,698,582; 5,714,512; and 5,750,561 (collectively, "sanofi-aventis' patents") are invalid, not infringed, and/or not enforceable. The letter also included a statement of factual and legal allegations on which Hospira based its certifications to the FDA.

ANSWER: Hospira admits the allegations of this paragraph.

FIRST COUNT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 5,714,512 B1

11. The allegations of the preceding paragraphs 1-10 are repeated, realleged, and incorporated herein by reference.

ANSWER: Hospira incorporates by reference its answers to paragraphs 1-10.

12. United States Patent No. 5,714,512 B1 ("the '512 patent"), entitled "New Compositions Containing Taxane Derivatives," was duly and legally issued by the United States Patent and Trademark Office on February 3, 1998. Aventis Pharma S.A. is the owner by assignment of the '512 patent and had the right to sue for infringement thereof. A true and correct copy of the '512 patent is attached as Exhibit A.

ANSWER: Hospira admits that the '512 patent states on its face an issue date of February 3, 1998. Hospira denies the remaining allegations of this paragraph.

13. Upon information and belief, Hospira's Paragraph IV certification alleged that Hospira's docetaxel injection product will not infringe claims 1-35 of the '512 patent, that claims 24-27 and 32-33 of the '512 patent are invalid, and/or that the patent is unenforceable.

ANSWER: Hospira admits that it submitted a Paragraph IV certification alleging that the claims of the '512 patent are invalid, not infringed, and/or unenforceable.

14. Under 35 U.S.C. § 271(e)(2)(A), Hospira's submission to the FDA of NDA No. 22-234 to obtain approval for the commercial manufacture, use, or sale of its docetaxel injection product before the expiration date of the '512 patent constitutes infringement of one or more claims of the '512 patent.

ANSWER: Hospira admits that its filing of NDA 22-234 vests this Court with subject matter jurisdiction. Hospira denies the remaining allegations of this paragraph.

15. Upon FDA approval of NDA No. 22-234, Hospira will infringe the '512 patent by making, using, offering to sell, selling, and/or importing the docetaxel injection product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless the Court orders that the effective date of any FDA approval of Hospira's NDA shall be no earlier than the expiration date of the '512 patent.

ANSWER: Hospira denies the allegations of this paragraph.

16. Upon information and belief, Hospira's docetaxel injection product, when offered for sale, sold, and/or imported, and then used as directed, would be used in a manner that would directly infringe at least one of the claims of the '512 patent.

ANSWER: Hospira denies the allegations of this paragraph.

17. Upon information and belief, the use of Hospira's docetaxel injection product constitutes a material part of at least one of the claims of the '512 patent; Hospira knows that is docetaxel injection product is especially made or adapted for use in infringing at least on of the claims of the '512 patent; and Hospira's docetaxel injection product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Hospira denies the allegations of this paragraph.

18. Upon information and belief, the offering to sell, sale, and/or importation of Hospira's docetaxel product would contributorily infringe at least one of the claims of the '512 patent.

ANSWER: Hospira denies the allegations of this paragraph, and objects to sanofi-aventis' allegation based on information and belief.

19. Upon information and belief, Hospira had knowledge of the '512 patent and, by its promotional activities and package insert for its docetaxel injection product, knows or should know that it will actively aid and abet another's direct infringement of at least one of the claims of the '512 patent.

ANSWER: Hospira denies the allegations of this paragraph.

20. Upon information and belief, the offering to sell, sale, and/or importation of Hospira's docetaxel injection product would actively induce infringement of at least one of the claims of the '512 patent.

ANSWER: Hospira denies the allegations of this paragraph, and objects to sanofi-aventis' allegation based on information and belief.

21. Sanofi-aventis will be substantially and irreparably harmed by Hospira's infringing activities unless those activities are enjoined by this Court. Sanofi-aventis has no adequate remedy at law.

ANSWER: Hospira denies the allegations of this paragraph.

SECOND COUNT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 5,750,561 B1

22. The allegations of the preceding paragraphs 1-21 are repeated, realleged, and incorporated herein by reference.

ANSWER: Hospira incorporates by reference its answers to paragraphs 1-21.

23. United States Patent No. 5,750,561 B1 ("the '561 patent", entitled "Compositions Containing Taxane Derivatives," was duly and legally issued by the United States patent and Trademark Office on May 12, 1998. Aventis Pharma S.A. is the owner by assignment of the '561 patent and has the right to sue for infringement thereof. A true and correct copy of the '561 patent is attached as Exhibit B.

ANSWER: Hospira admits that the '561 patent states on its face an issue date of May 12, 1998. Hospira denies the remaining allegations of this paragraph.

24. Upon information and belief, Hospira's Paragraph IV certification alleged that Hospira's docetaxel injection product will not infringe claims 1-11 of the '561 patent and that claims 1-11 should be held invalid if those claims are construed to be infringed by Hospira's product. Upon information and belief, no allegations of unenforceability of claims 1-11 of the '561 patent have been made.

ANSWER: Hospira admits that it submitted a Paragraph IV certification alleging that the claims of the '561 patent are invalid, not infringed, and/or unenforceable.

25. Under 35 U.S.C. § 271(e)(2)(A), Hospira's submission to the FDA of NDA No. 22-234 to obtain approval for the commercial manufacture, use, or sale of its docetaxel injection product before the expiration date of the '561 patent constitutes infringement of one or more claims of the '561 patent.

ANSWER: Hospira admits that its filing of NDA 22-234 vests this Court with subject matter jurisdiction. Hospira denies the remaining allegations of this paragraph.

26. Upon FDA approval of NDA No. 22-234, Hospira will infringe the '561 patent by making, using, offering to sell, selling, and/or importing the docetaxel injection product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Hospira's NDA shall be no earlier than the expiration date of the '561 patent.

ANSWER: Hospira denies the allegations of this paragraph.

27. Upon information and belief, Hospira's docetaxel injection product, when offered for sale, sold, and/or imported, and then used as directed, would be used in a manner that would directly infringe at least one of the claims of the '561 patent.

ANSWER: Hospira denies the allegations of this paragraph.

28. Upon information and belief, the use of Hospira's docetaxel injection product constitutes a material part of at least one of the claims of the '561 patent; Hospira knows that its docetaxel injection product is especially made or adapted for use in infringing at least one of the claims of the '561 patent; and Hospira's docetaxel injection product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Hospira denies the allegations of this paragraph.

29. Upon information and belief, the offering to sell, sale, and/or importation of Hospira's docetaxel product would contributorily infringe at least one of the claims of the '561 patent.

ANSWER: Hospira denies the allegations of this paragraph, and objects to sanofi-aventis' allegation based on information and belief.

30. Upon information and belief, Hospira had knowledge of the '561 patent and, by its promotional activities and package insert for its docetaxel injection product, knows or should know that it will actively aid and abet another's direct infringement of at least one of the claims of the '561 patent.

ANSWER: Hospira denies the allegations of this paragraph.

31. Upon information and belief, the offering to sell, sale, and/or importation of Hospira's docetaxel injection product would actively induce infringement of at least once of the claims of the '561 patent.

ANSWER: Hospira denies the allegations of this paragraph, and objects to sanofi-aventis' allegation based on information and belief.

32. Sanofi-aventis will be substantially and irreparable harmed by Hospira's infringing activities unless those activities are enjoined by this Court. Sanofi-aventis has no adequate remedy at law.

ANSWER: Hospira denies the allegations of this paragraph.

HOSPIRA'S AFFIRMATIVE DEFENSES

First Affirmative Defense

Plaintiffs are not entitled to relief because they have not appropriately shown nor proven adequate standing for the relief sought.

Second Affirmative Defense

Plaintiffs are not entitled to relief because they are estopped by the prosecution histories for the asserted patents and subject to prosecution history laches.

Third Affirmative Defense

The claims of the asserted patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation.

Fourth Affirmative Defense

The asserted patents are unenforceable due to inequitable conduct before the PTO, for at least the reasons discussed in Hospira's Counterclaims identified below.

Fifth Affirmative Defense

Hospira does not infringe, and if marketed would not infringe, any valid and enforceable claim of the asserted patents with the products that are the subject of NDA 22-234.

WHEREFORE, Hospira hereby demands judgment dismissing Plaintiffs' Complaint with prejudice, judgment for costs and fees for suit, and for such other relief as the Court may deem just.

COUNTERCLAIMS

For its counterclaims against Plaintiffs and Counter-Defendants Aventis Pharma S.A. and sanofi-aventis U.S., LLC (collectively, "sanofi-aventis"), Defendant and Counter-Plaintiff Hospira, Inc. states as follows:

Parties, Jurisdiction, and Venue

1. Hospira, Inc. is a Delaware corporation having corporate offices and a principal place of business at 275 Field Dr., Lake Forest, Illinois 60045.

2. On information and belief, Aventis Pharma S.A. is a French corporation with its principle place of business in Paris, France, and sanofi-aventis U.S., LLC is a Delaware corporation with its principal place of business in Bridgewater, New Jersey.

3. This action arises under the patent laws of the United States. Subject matter jurisdiction is proper in this Court by Title 28, U.S.C. Sections 1331, 1338(a), 2201, and/or 2202.

4. Personal jurisdiction is proper in this Court as to Aventis Pharma S.A. because it has subjected itself to the jurisdiction of this Court by virtue of filing its Complaint. Personal jurisdiction is proper in this Court as to sanofi-aventis U.S., LLC because it is a Delaware corporation and because it has subjected itself to the jurisdiction of this Court by virtue of filing its Complaint.

5. Venue is proper in this Court under Title 28, U.S.C. 1391 and 1400.

Background

6. The United States Patent and Trademark Office issued U.S. Patent Nos. 5,714,512 ("the '512 patent") and 5,750,561 ("the '561 patent"), naming Rhone-Poulenc Rorer S.A. as the assignee. Aventis Pharma S.A. and sanofi-aventis claim to have right, title, and interest in these patents.

7. On information and belief, sanofi-aventis is the current holder of approved New Drug Application ("NDA") No. 020-449 for a docetaxel injection product, which has the proprietary name Taxotere®.

8. The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act require NDA holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holders believe claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

9. Sanofi-aventis listed the '512 and '561 patents in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" which is commonly called the "Orange Book."

10. Hospira submitted to the FDA a certification, commonly called a "paragraph IV certification" that the '512 and '561 patents are invalid, unenforceable, and/or not infringed by its proposed generic product.

11. Sanofi sued Hospira alleging infringement of the '512 and '561 patents. There has been and is now an actual and justiciable controversy between Hospira and sanofi-aventis as to whether Hospira's proposed 505(b)(2) docetaxel injection product infringes, induces infringement, or contributes to the infringement of any valid claim of the '512 and '561 patents.

12. This case is an exceptional one, and Hospira is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

COUNT I

Declaration of Non-Infringement and/or Invalidity of the '512 Patent

13. Hospira re-alleges and incorporates the allegations of all the above paragraphs.

14. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '512 and '561 patents will be infringed by the manufacture, use, offer for sale, or sale of Hospira's 505(b)(2) products.

15. Sanofi-aventis asserts that the manufacture, use, offer for sale, or sale of Hospira's 505(b)(2) products do and will infringe claims of the '512 patent.

16. The manufacture, use, offer for sale, or sale of Hospira's 505(b)(2) products do not and will not infringe any valid claim of the '512 patent, because the claims are unenforceable, not infringed, and/or invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 or 112, or other judicially-created bases for invalidation.

17. A present, genuine justiciable controversy therefore exists between Hospira and sanofi-aventis regarding the issue of whether the manufacture, use, offer for sale, or sale of Hospira's 505(b)(2) products would infringe valid claims of the '512 patent.

18. Hospira is entitled to a declaration that the manufacture, use, offer for sale, and sale of its 505(b)(2) products do not and will not infringe any valid claim of the '512 patent.

COUNT II

Declaration of Non-Infringement and/or Invalidity of the '561 Patent

19. Hospira re-alleges and incorporates the allegations of all the above paragraphs.

20. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '512 and '561 patents will be infringed by the manufacture, use, offer for sale, or sale of Hospira's 505(b)(2) products.

21. Sanofi-aventis asserts that the manufacture, use, offer for sale, or sale of Hospira's 505(b)(2) products do and will infringe claims of the '561 patent.

22. The manufacture, use, offer for sale, or sale of Hospira's 505(b)(2) products do not and will not infringe any valid claim of the '561 patent, because the claims are unenforceable, not infringed, and/or invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 or 112, or other judicially-created bases for invalidation.

23. A present, genuine justiciable controversy therefore exists between Hospira and sanofi-aventis regarding the issue of whether the manufacture, use, offer for sale, or sale of Hospira's 505(b)(2) products would infringe valid claims of the '561 patent.

24. Hospira is entitled to a declaration that the manufacture, use, offer for sale, and sale of its 505(b)(2) products do not and will not infringe any valid claim of the '561 patent.

COUNT III

Declaration of Unenforceability of the '512 and '561 Patents

25. Hospira re-alleges and incorporates the allegations of all the above paragraphs.

26. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '512 and '561 patents are unenforceable by virtue of inequitable conduct by the named inventors, prosecuting attorneys, patent assignees, Rhone-Poulenc Rorer S.A., sanofi-aventis, Aventis Pharma, and/or others substantially involved in the prosecution of these or related patents (collectively, the "applicants").

27. Sanofi-aventis asserts that the manufacture, use, offer for sale, or sale of Hospira's 505(b)(2) products do and will infringe enforceable claims of the '512 and '561 patents.

28. The manufacture, use, offer for sale, or sale of Hospira's 505(b)(2) products do not and will not infringe any enforceable claim of the '512 and '561 patents, because the claims are unenforceable by virtue of Hospira's inequitable conduct.

29. During prosecution of the '512 patent, there were 35 pending claims. In a rejection dated November 27, 1996, the U.S. Patent & Trademark Office ("PTO") rejected those pending claims over the prior art, which disclosed taxane structures.

30. On February 24, 1997, the applicants for the '512 patent responded to the prior art rejection by arguing that the claim limitation "essentially free of alcohol" distinguished the prior art, because the prior art cited by the PTO "does not teach or suggest new solutions of Taxol derivatives such as those presently disclosed with less Cremaphor or ethanol" in order to avoid alcohol poisoning. That limitation was not in all of the pending claims.

31. After the applicants made this argument, the PTO then issued a notice of allowability on May 23, 1997. The notice expressly confirmed the PTO's reliance on the applicants' argument that the prior art did not have solutions "that do not cause anaphylactic shock or alcohol poisoning."

32. After the allowance, the applicants then sought to amend the claims to include the limitation "essentially free or free of alcohol." In a statement dated September

11, 1997, the PTO allowed the change and reported that the "claims will read free of alcohol."

33. Despite the applicants' argument and the PTO's requirement, applicants failed to modify all of the pending claims. Specifically, in an amendment dated October 20, 1997, applicants amended claims 1 through 23 to read "essentially free or free of alcohol," but applicants did not amend claims 24 through 35 to add this limitation.

34. Prosecuting a patent application is an *ex parte* process, and patent applicants are subject to the duties of good faith, candor, and disclosure, among others. *See* 37 C.F.R. § 1.56; Manual of Patent Examining Procedure (MPEP) § 2000.

35. The applicants' failure to amend claims 24 through 35 breached the duties of good faith, candor, and/or disclosure. Failure to amend claims 24 through 35 was material to patentability of the pending claims, particularly where the patent examiner already expressed the importance of the amendment to the patentability of these claims.

36. The '512 patent issued without including the required "essentially free or free of alcohol" claim limitation for claims 24 through 35. This resulted in claims 24 through 35 having an unfairly broader scope than claims 1 through 23. The broader scope should not have been allowed because inclusion of "essentially free or free of alcohol" was required by the applicants' argument and admissions and was the basis on which the PTO allowed the claims.

37. Upon information and belief, and based upon a reasonable inference due to the high materiality of the failure to amend pending claims 24 through 35 of the application

that resulted in the ‘512 patent, the named inventors, prosecuting attorneys, patent assignees, Rhone-Poluenc Rorer S.A., sanofi-aventis, Aventis Pharma, and/or others substantially involved in the prosecution of these or related patents intentionally failed to amend claims 24 through 35 during prosecution of the ‘512 patent.

38. The named assignee that prosecuted the ‘512 patent was Rhone-Poulenc Rorer, S.A. The ‘561 patent names this same common assignee.

39. The ‘512 patent lists Jean-Pierre Bastart, Thierry Dupechez, and Jean-Louis Fabre as named co-inventors. The ‘561 patent names these same co-inventors.

40. The ‘512 and ‘561 patents both claim priority to the same ultimate parent application, Serial No. 930,392, which resulted in U.S. Patent No. 5,403,858 (“the ‘858 patent”). Application Serial No. 930,392 was filed August 23, 1993.

41. The ‘512 and ‘561 patents are related because they are in the same family tree, stem from the same parent application Serial No. 930,392, were at all times commonly assigned, were prosecuted by the same law firm, and are related to the same or substantially the same subject matter.

42. The ‘512 and ‘561 patents are both listed by sanofi-aventis in the Orange Book for docetaxel injection products.

43. Upon information and belief, the ‘512 and ‘561 patents were allegedly transferred to Aventis Pharma S.A., on or about December 20, 1999.

44. The inequitable conduct during prosecution of the ‘512 patent infects and renders unenforceable the ‘561 patent.

45. Another ground for inequitable conduct is that the applicants failed to disclose material prior art to the PTO. The ‘512 and ‘561 patents were pending before the Patent Office at the same time. Also at about the same time, the same applicants were prosecuting and had knowledge of the application process that resulted in U.S. Patent Nos. 5,438,072 and 5,698,582.

46. Upon information and belief, one or more of the same individuals at the relevant assignee entity were commonly involved in the preparation and/or prosecution of the ‘072 patent and/or the ‘582 patent, along with the ‘512 patent and/or ‘561 patent.

47. Nonetheless, the applicants failed to disclose in connection with the ‘512 patent the prior art references that had been cited during the prosecution of the ‘561, ‘582, and ‘072 patents. For example, the applicants did not disclose U.S. Patent No. 4,814,470 issued to Colin; U.S. Patent No. 4,507,217 issued to Sears; U.S. Patent No. 4,534,899 issued to Sears; EPO 0118316; EPO 0253738; EPO 0522937; WO93/00928; WO93/00929; WO92/09589; WO93/16060; WO93/21173; WO94/12484; Chemical Abstracts 106, No. 22, abstract 182581c (1987); Agent, E. Rowinsky et al., “Taxol: A Novel Investigational Antimicrotubule,” J. National Cancer Inst., v. 82, no. 15, at 1247-59 (1990); U.S. Patent No. 5,254,580 issued to Chen; U.S. Patent No. 5,272,171 issued to Ueda; Chemical Abstract vol. 106(22) 152581c Terry (1987); Chemical Abstract vol. 106(22) 182581c Tarr (1987); Merck Index, 11th Edition #7559 (1987); and Tarr “A New Parenteral Vehicle for

the Administration of Some Poorly Water Soluble Anti-Cancer Drugs," J. Parenter. Sci. Technol. 41 (1), 31-33 (1987).

48. Similarly, the applicants failed to disclose in connection with the '561 patent the prior art references that had been cited during the prosecution of the '512, '582, and '072 patents. For example, the applicants did not disclose U.S. Patent No. 4,507,217 issued to Sears; U.S. Patent No. 4,534,899 issued to Sears; EPO 0118316; EPO 0253738; EPO 0522937; WO93/00928; WO93/00929; WO92/09589; WO93/16060; WO93/21173; WO94/12484; Agent, E. Rowinsky et al., "Taxol: A Novel Investigational Antimicrotubule," J. National Cancer Inst., v. 82, no. 15, at 1247-59 (1990); U.S. Patent No. 5,254,580 issued to Chen; U.S. Patent No. 5,272,171 issued to Ueda; Chemical Abstract vol. 106(22) 152581c Terry (1987); and Tarr "A New Parenteral Vehicle for the Administration of Some Poorly Water Soluble Anti-Cancer Drugs," J. Parenter. Sci. Technol. 41 (1), 31-33 (1987).

49. All of the undisclosed prior art references in the preceding paragraphs were material to patentability and were not merely cumulative. The prior art references were important to patentability, a patent examiner would consider them important to patentability, and the references contradicted or limited arguments made by the applicants during prosecution of the respective patent applications. The patents were selectively disclosed in some but not all of the patent application files.

50. Section 2001.06 of the MPEP required applicants and others involved in the prosecution of these patents to bring to the attention of the PTO any material prior art or other information cited known to the applicant. The applicants' failure to disclose all

pertinent prior art during prosecution of each of the ‘512 and ‘561 patents violated this Section and breached the duties of good faith, candor, and disclosure.

51. The applicants’ failure to disclose all pertinent prior art during prosecution of the ‘512 and ‘561 patents was especially significant and material because the same patent Examiner did not review and examine all of these patents. Examiner Amelia Owens reviewed the ‘512 patent while Examiner Theodore Criares reviewed the ‘561 patent.

52. Upon information and belief, and based upon a reasonable inference due to the high materiality of failure to disclose all the pertinent prior art during prosecution, the named inventors, prosecuting attorneys, patent assignees, Rhone-Poulenc Rorer S.A., sanofi-aventis, Aventis Pharma, and/or others substantially involved in the prosecution of these or related patents intentionally failed to disclose all pertinent prior art that was known to them during prosecution of the ‘512 and ‘561 patents.

53. The inequitable conduct during prosecution of any one of the ‘512, ‘561, ‘582, and ‘072 patents infects and renders unenforceable the ‘512 and ‘561 patents.

54. A present, genuine justiciable controversy exists between Hospira and sanofi-aventis regarding the unenforceability of the ‘512 and ‘561 patents.

55. Hospira is entitled to a declaration that the ‘512 and ‘561 patents are unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Defendant/Counter-Plaintiff Hospira, Inc. prays that the Court enter judgment in its favor and against Plaintiff/Counter-Defendants Aventis Pharma S.A. and sanofi-aventis U.S., LLC as follows:

a) Granting a declaration that Hospira's 505(b)(2) products do not and will not infringe any valid claim of the '512 and '561 patents;

b) Granting a declaration that the claims of the '512 and '561 patents are invalid;

c) Granting a declaration that the '512 and '561 patents are unenforceable;

d) Declaring this an exceptional case in favor of Hospira, Inc. and awarding attorneys' fees pursuant to 35 U.S.C. § 285;

e) Awarding costs and expenses; and

f) Awarding any and all such other relief as the Court determines to be just and proper.

Dated: December 10, 2007

/s/ Richard K. Herrmann

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